Remarks

Claims 1, 8, 9, 16, and 30 have been amended. Claims 6, 31, and 32 have been cancelled. Claims 1-5, 7-9, 16, 30 and 33 remain in the application. The claim amendments made herein track the amendments discussed with the Examiner in a telephonic interview on May 22, 2003. Entry and allowance of these claims as now amended is respectfully requested.

Claim Objections

Claims 6 and 30-33 stand objected to under 37 CFR §1.75(c) as being in improper form. The claims have been amended as requested by the Examiner to address the objections under 37 CFR §1.75(c).

Rejection of Claims Under 35 U.S.C. §103

Claims 1-9, 16, 30, 32, and 33 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Watts et al. (U.S. 6,200,602). The Watts et al. '602 patent is generally directed to a drug delivery composition for colonic delivery. In particular, Watts et al. '602 disclose a composition that prevents release of the polar drug until the formulation reaches the colon (column 6, lines 21-24).

By contrast, the presently claimed oral drug delivery composition provides a formulation for dissolving at least

80% of the drug within five (5) minutes of exposure to simulated intestinal fluid (see page 4, lines 11-15 and page 11, lines 4-8). As such, the composition of the present invention is formulated so as to substantially dissolve quickly within the small intestine (see page 7, lines 22-24 and page 7, line 11-page 8, line 2), and preferably substantially before reaching the colon, as is described in Watts et al. '602. In fact, Watts et al. '602 actually teach away from the claimed rapid drug dissolution at column 6, lines 48-51, wherein the capsule of Watts et al. '602 will dissolve only after 3-4 hours of exposure to intestinal fluid so as to break up only when it has reached the terminal ileum or the colon. Therefore, Watts et al. '602 specifically teach away from a quickly dissolving composition, as is presently claimed.

In addition, nowhere do Watts et al. '602 teach or suggest the presently claimed ratios of disintegrant to drug for rapidly dissolving the drug in intestinal fluids. Such a ratio of disintegrant to the drug is an important aspect in the preferred rapid dissolution of the drug in intestinal fluid, and is described as such on, for example, page 17, lines 10-23 of the application as originally filed. Moreover, a Declaration of Alexander J. Wigmore, the named inventor in the present application, is enclosed

herewith for distinctly identifying the importance and unexpected nature of the presently claimed ratios of disintegrant to drug in effecting rapid dissolution of such drug in intestinal fluid. Most particularly, the claimed ratios in the compositions of the present invention overcome a gelling effect that inhibits dissolution of the drug in intestinal fluid. Nowhere do Watts et al. '602 teach or suggest such a means for effecting expedient polar drug dissolution in intestinal fluid. The Examiner asserts that the tablet or pellet of Watts et al. '602 would have similar dissolve rates desired by the Applicant. Applicant respectfully submits, however, that no teaching of the claimed disintegrant to drug ratios that are critical to the drug dissolve rates of the present invention is found in Watts et al. '602. The claim rejections based upon Watts et al. '602 should accordingly be withdrawn.

For the foregoing reasons, the claims as presently amended are believed to be unobvious and patentable over the cited prior art, and particularly over Watts et al. '602. Applicant therefore submits that the claims as currently presented are allowable on the merits. An early allowance is respectfully solicited.

Respectfully submitted,

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